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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,105	11/25/2003	Andrew K. Benson	101997-0019	4844
21125	7590	08/24/2005	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			RIGGINS, PATRICK S	
			ART UNIT	PAPER NUMBER
			1633	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/722,105

Applicant(s)

BENSON, ANDREW K.

Examiner

Patrick S. Riggins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,9,12-22 and 44 is/are rejected.
- 7) ☒ Claim(s) 2,3,10 and 11 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/9/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Drawings

1. It appears, based on the description of Examples 2 and 3 that Figures 5 and 6 are color photographs.
2. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 100. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

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applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities: In the Brief Description of Drawings in paragraph 0014 "Figure 2" should read --Figures 2A-2B--. Examples 2 and 3 on pages 27-29 discuss Figures 5 and 6, referring to colors in the Figures. As the Figures are in fact in black and white, these descriptions are meaningless.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 9 recites that the physical characteristic is selected from a group consisting of a variety of characteristics including pH and acidity. It is unclear what the difference is between pH and acidity since pH is the measure of acidity.

8. Claim 13 is vague and indefinite because it depends from itself. Therefore there is no way to know what the further limitations entail. For the purposes of examination, claim 13 will be presumed to depend from claim 12.

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9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

11. Claim 4 is drawn to a method where another food product is assayed in the manner claimed in claim 1. The purpose of this is to compare the result from this food sample to the database results produced in claim 2 in order to determine if the other food product possesses the target characteristic to which the output distribution was correlated. To practice this embodiment of this invention, one would need to have the database that claims 1 and 2 seek to produce. As the purpose of claim 1 is to establish this database for future use, it would seem that the database does not yet exist in this regard.

12. It would seem then that the skilled artisan would need evidence of possession of this sort of correlative database to suggest that the applicant was able to practice the method of claim 4. For this one looks to specification to determine what the applicant had exemplified. Example 1 sets to determine the specificity and sensitivity of a multispecies array of the invention. Thus DAN was extraction directly from various bacterial species, not from foodstuffs comprising these bacterial species. Example 2 was set to identify probes that would act in a species-specific manner. Example 3 is the closes example to practicing the invention, however, the ground beef

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used as the food sample in this example was spiked with *Listeria*. This was merely to exemplify that the bacteria could be purified from a foodstuff and did not contain any true knowledge of any property of the ground beef, and thus there was no correlation of the presence of *Listeria* in the beef to any property.

13. It is thus clear that applicant had not yet established a database correlating microbial content of food products to various sensory or physical characteristics, processing conditions, or ingredient information of the food products as of the time of filing. Therefore there is no evidence of record to suggest to the skilled artisan that applicant was in possession of any such database. In the absence of this database one would be unable to process an additional foodstuff to determine its microbial content in order to assign a certain characteristic. In short, the absence of the database precludes one from performing the method of claim 4. As such, there is no evidence to suggest to the skilled artisan that the applicant was in possession of the method of claim 4 at the time of filing.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. The majority of limitations in claims 15-22 are intended use types of limitations. Thus it is only the product that must appear in the prior art to anticipate intended use claims, as the

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intended use bears little patentable weight unless the intended use somehow alters the physical properties of the product. Claims 15-22 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No 2002/0086289 (hereinafter Straus). Straus discloses a method for identifying organisms in a complex biological sample using hybridization to arrays. Thus Figure 4 depicts a multispecies array (see especially the top example). As paragraph 0308 states, the arrays are scanned and the signals processed electronically. The obtained data is then stored and correlated with specific traits or use in future assays. For example, information from the assays could aid in diagnosis and the information would be processed to allow for appropriate treatment options (see e.g. paragraph 0135). Thus each physical limitation of claim 15 is met. A wide variety of arrays are contemplated where probes are present to identify the same gene sequences or alternatively or in combination with probes present to differentiate between different sequences (see particularly pages 3-5). The method can be used to quantify the level of an organism in the biological sample tested (see paragraph 0032). Additionally, the procedures can be automated (paragraph 0047). It is noted that the biological sample can be derived from food (see paragraph 0103 and 0154). In this setting one would inherently include the system into a food processing line.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1, 5-8, and 12-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 9, 10, 13, 17, 18, and 21 of U.S. Patent No. 6,878,517, as follows: instant claim 1 over patent claims 1 and 9, instant claim 5 over patent claim 1, instant claim 6 over patent claims 2 and 3, instant claim 7 over patent claim 3, instant claim 8 over patent claims 18 and 21, instant claim 12 over patent claim 10, instant claim 13 over patent claim 13, and instant claim 14 over patent claim 17. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). Although the conflicting claims are not identical, they are not patentably distinct from each other because, in the case of instant claims 1, 5-8, and 12-14, they are generic to all that is recited in the respective claims of the patent, i.e. each of the patented claims is more specifically drawn than the instant claims.

Conclusion

18. Claims 2, 3, 10, and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kuipers (Curr Opin Biotechnol 10:511-516 (1999), newly cited) establishes the state of the art with regard to food testing at the time of filing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick S. Riggins whose telephone number is (571) 272-6102. The examiner can normally be reached on M-F 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick Riggins, Ph.D.
Examiner
Art Unit 1633



JAMES KETTER
PRIMARY EXAMINER